

BSS- balanced salt solution solution
Alcon Laboratories, Inc.

BSS®
Sterile Irrigating Solution
(balanced salt solution)

DESCRIPTION

BSS® Sterile Irrigating Solution is a sterile balanced salt solution, each mL containing sodium chloride (NaCl) 0.64%, potassium chloride (KCl) 0.075%, calcium chloride dihydrate ($\text{CaCl}_2 \cdot 2\text{H}_2\text{O}$) 0.048%, magnesium chloride hexahydrate ($\text{MgCl}_2 \cdot 6\text{H}_2\text{O}$) 0.03%, sodium acetate trihydrate ($\text{C}_2\text{H}_3\text{NaO}_2 \cdot 3\text{H}_2\text{O}$) 0.39%, sodium citrate dihydrate ($\text{C}_6\text{H}_5\text{Na}_3\text{O}_7 \cdot 2\text{H}_2\text{O}$) 0.17%, sodium hydroxide and/or hydrochloric acid (to adjust pH), and water for injection. The pH is approximately 7.5. The osmolality is approximately 300 mOsm/Kg.

CLINICAL PHARMACOLOGY

BSS Sterile Irrigating Solution is an isotonic solution for use in irrigating tissues of the eyes.

INDICATIONS AND USAGE

For use as an extraocular and intraocular irrigating solution during ocular surgical procedure involving perfusion of the eye with an expected maximum duration of less than 60 minutes.

WARNINGS

- NOT FOR INJECTION OR INTRAVENOUS INFUSION.
- Do not use unless product is clear, seal is intact, and container is undamaged.
- Do not use if product is discolored or contains a precipitate.
- SINGLE patient use only. The contents of this bottle should not be used in more than one patient.
- This solution contains no preservative, unused contents should be discarded.

PRECAUTIONS

Open under aseptic conditions only.

Prior to use, check the following: tip should be firmly in place, irrigating needle should be properly seated; squeeze out several drops before inserting into anterior chamber. The needle should be removed from the anterior chamber prior to releasing pressure to prevent suction.

Studies suggest that intraocular irrigating solutions which are iso-osmotic with normal aqueous fluids should be used with caution in diabetic patients undergoing vitrectomy since intraoperative lens changes have been observed.

There have been reports of corneal clouding or edema following ocular surgery in which BSS Sterile Irrigating Solution was used as an irrigating solution.

ADVERSE REACTIONS

Irrigation or any other trauma to the corneal endothelium may result in corneal swelling or bullous

keratopathy. Post-operative inflammatory reactions as well as incidents of corneal edema and corneal decompensation have been reported.

DOSAGE AND ADMINISTRATION

The adapter plug is designed to accept an irrigating needle. Tissues may be irrigated by attaching the needle to the DROP-TAINER® bottle as explained below. External irrigation may be done without the irrigating needle.

Method of using Adapter Plug for LUER-LOK® Hub Ophthalmic Irrigating Needle:

1. Aseptically remove DROP-TAINER bottle from blister by peeling paper backing.
2. Snap on surgeon's sterile irrigation needle. Push until firmly in place and twist slightly.
3. Test assembly for proper function before use.

NOTE: LUER-LOK is a registered trademark of Becton, Dickinson and Company.

HOW SUPPLIED

In 15 mL and 30 mL sterile DROP-TAINER bottles (consisting of a polypropylene bottle and LEURLOK® adapter plug with a white polypropylene closure) in a blister package.

15 mL in a 15 mL bottle:

NDC0065-0795-15

30 mL in a 30 mL bottle:

NDC0065-0795-30

STORAGE: Store at 36° - 77°F (2° - 25°C).

Revised: November 2015

Alcon®

A Novartis company

Distributed by:

Alcon Laboratories , Inc.

6201 South Freeway

Fort Worth, Texas 76134 USA

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9012634-1115

PRINCIPAL DISPLAY PANEL

NDC 0065-0795-15

BSS®

Sterile Irrigating Solution

(balanced salt solution)

ALCON®

a Novartis company

CONTENTS: 3 doz. 15mL Single Dose Bottles

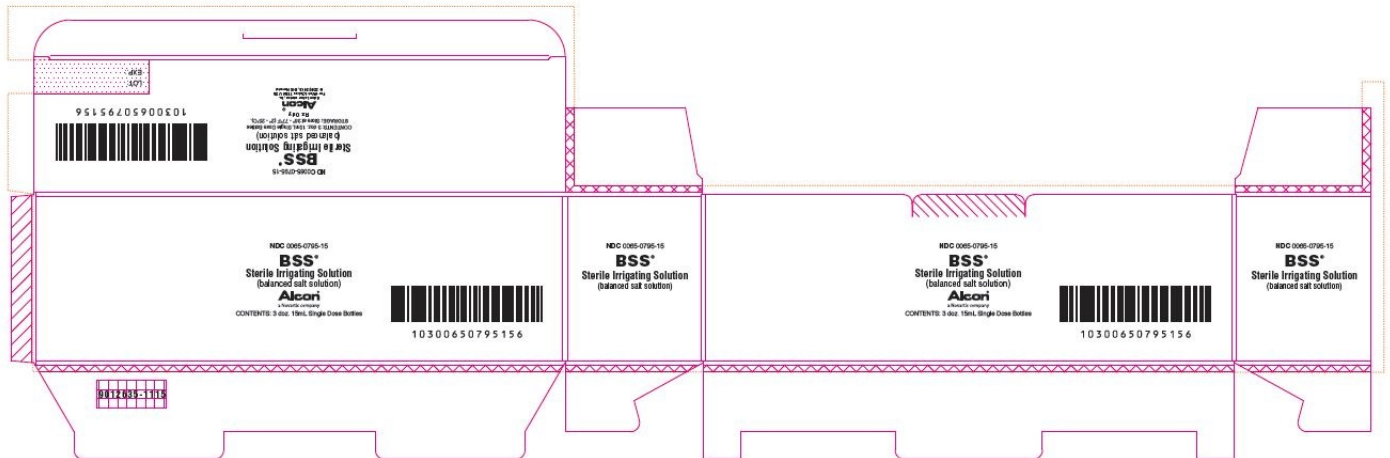
STORAGE: Store at 36° - 77°F (2° - 25°C).

Rx Only

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NDC 0065-0795-15

BSS®
Sterile Irrigating Solution
(balanced salt solution)

STERILE UNLESS PACKAGE OPEN OR BROKEN

15 mL DROP-TAINER® Bottle, SINGLE DOSE UNIT With Adapter for LUER-LOK® Hub Irrigating Needle

A sterile balanced salt solution for extraocular and intraocular use during procedures with an expected maximum duration of less than 60 minutes. Read enclosed insert.

WARNINGS:

- **NOT FOR INJECTION OR INTRAVENOUS INFUSION.**
- **Do not use unless product is clear, seal is intact and container is undamaged.**
- **Do not use if blister or paper backing is damaged or broken.**
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- **SINGLE patient use only. The contents of this bottle should not be used in more than one patient.**
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PRECAUTIONS: Open under aseptic conditions only.

Rx Only

Each mL contains: sodium chloride 0.64%, potassium chloride 0.075%, calcium chloride dihydrate

0.048%, magnesium chloride hexahydrate 0.03%, sodium acetate trihydrate 0.39%, sodium citrate dihydrate 0.17%, sodium hydroxide and/or hydrochloric acid (to adjust pH), and water for injection.

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NDC 0065-0795-15

BSS[®]

Sterile Irrigating Solution
(balanced salt solution)

STERILE UNLESS PACKAGE OPEN OR BROKEN
15 mL DROP-TAINER[®] Bottle, SINGLE DOSE UNIT
With Adapter for LUER-LOK[®] Hub
Irrigating Needle

A sterile balanced salt solution for extraocular and intraocular use during procedures with an expected maximum duration of less than 60 minutes. Read enclosed insert.

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BSS[®]

STERILE IRRIGATING SOLUTION

(BALANCED SALT SOLUTION)

UNIT DOSE 15 mL

Rx Only

ALCON LABORATRIES, INC.
FORT WORTH
TEXAS 76134 USA

289010-0902

NDC 0065-0795-15

BSS[®]

STERILE IRRIGATING
SOLUTION
(BALANCED SALT
SOLUTION)
UNIT DOSE
15 mL

Rx Only

ALCON LABORATORIES, INC.
FORT WORTH
TEXAS 76134 USA
289010-0902

BSS

balanced salt solution solution

Product Information

Product Type

HUMAN PRESCRIPTION DRUG

Item Code (Source)

NDC:0065-0795

Route of Administration

OPHTHALMIC

Active Ingredient/Active Moiety

Ingredient Name

SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37)

Basis of Strength

SODIUM CHLORIDE

Strength

6.4 mg in 1 mL

Ingredient Name

POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152)

Basis of Strength

POTASSIUM CHLORIDE

Strength

0.75 mg in 1 mL

Ingredient Name

CALCIUM CHLORIDE (UNII: M4I0D6VV5M) (CALCIUM CATION - UNII:2M83C4R6ZB)

Basis of Strength

CALCIUM CHLORIDE

Strength

0.48 mg in 1 mL

Ingredient Name

MAGNESIUM CHLORIDE (UNII: 02F3473H9O) (MAGNESIUM CATION - UNII:T6V3LHY838)

Basis of Strength

MAGNESIUM CHLORIDE

Strength

0.3 mg in 1 mL

Ingredient Name

SODIUM ACETATE (UNII: 4550K0SC9B) (SODIUM CATION - UNII:LYR4M0NH37)

Basis of Strength

SODIUM ACETATE

Strength

3.9 mg in 1 mL

Ingredient Name

SODIUM CITRATE (UNII: 1Q73Q2JULR) (SODIUM CATION - UNII:LYR4M0NH37)

Basis of Strength

SODIUM CITRATE

Strength

1.7 mg in 1 mL

Inactive Ingredients				
Ingredient Name				Strength
SODIUM HYDROXIDE (UNII: 55X04QC32I)				
HYDROCHLORIC ACID (UNII: QTT17582CB)				
WATER (UNII: 059QF0K00R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0065-0795-15	15 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/28/1969	
2	NDC:0065-0795-30	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/28/1969	12/31/2018
3	NDC:0065-0795-25	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/28/1969	04/17/2015
4	NDC:0065-0795-50	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/28/1969	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA		NDA020742	03/28/1969	

Labeler - Alcon Laboratories, Inc. (008018525)

Registrant - Alcon Laboratories, Inc. (008018525)

Establishment			
Name	Address	ID/FEI	Business Operations
Alcon Research LLC		007672236	manufacture(0065-0795)

Establishment			
Name	Address	ID/FEI	Business Operations
S.A. Alcon-Couvreur N.V.		370205429	manufacture(0065-0795)